

MIDWESTERN UNIVERSITY

STANDARD POLICY

DIVISION: All University Colleges

CAMPUS: Downers Grove and Glendale

SUBJECT: Institutional Research	POLICY NO. 0001		
APPROVED BY:  Arthur G. Dobbelaere, Ph.D., Executive Vice President/COO	ISSUE DATE 1/25/17	SUPERSEDES 12/98	PAGES 3

PURPOSE

This policy outlines institutional requirements for the preparation and review of intramurally and extramurally funded research proposals.

POLICY

The term "research" applies to organized investigations or experimental observations aimed at the discovery and interpretation of new facts. It may involve special experimental conditions arranged by an individual in order to test a hypothesis, to discover some unknown principle or effect, or to illustrate some known or suggested truth. Research may also include surveys, interviews, tests, observations, or experimental conditions imposed by an individual to elicit new knowledge about individuals or groups.

Excluded from this definition are activities whose sole purpose is instructional in nature and which are not carried out to gain new information.

Also excluded are activities whose purpose is related to routine course or program development and/or evaluation.

A faculty member may conduct **informal or preliminary studies** that do not involve human or animal subjects, biologically hazardous materials, recombinant DNA or radioisotopes, provided that the investigator has the approval of their department chair or program director. However, once an activity continues beyond trial or exploratory stage and the principal investigator (PI) seeks extramural funding, it must be submitted in a formal proposal to the Office of Research and Sponsored Programs (ORSP) for review as an organized research activity. Similarly, once an activity continues beyond trial or exploratory stage and the PI seeks intramural funding, it must be submitted in a formal proposal to the college using the format required by the college.

Individuals who hold the rank of postdoctoral fellow, instructor, research track faculty, or tenure track faculty may serve as PI or Co-PI on an extramural proposal. Others may use the "Request for Approval to Serve as Principal Investigator on an IRB Protocol or Grant" form. Appropriate administrative offices and/or institutional committees must approve all organized research activities conducted at Midwestern University (MWU) involving human or animal subjects, biologically hazardous materials, recombinant DNA or radioisotopes in advance of initiating the research. Any question as to whether an activity is defined as research or the process for appropriate approval should be addressed to the ORSP.

The proposal seeking extramural funding describing the organized research activity must be submitted to the ORSP in a **formal proposal** with a completed "**Proposal Approval Form**" (available on the ORSP website) signed by the department chair or program director and college dean. This form is provided to obtain the necessary administrative approvals prior to submission of the proposal to the

ORSP. Applications not accompanied by a completed Proposal Approval Form will be considered incomplete and returned to the applicant.

In addition to the required Proposal Approval Form, a principal investigator must submit a final detailed grant budget and budget justification to the ORSP for review at least two (2) weeks in advance of any grant deadline. An internal detailed budget is required with every proposal whether the sponsor requires a modular budget or only a total dollar amount. The grant budget must be approved by the ORSP before the PI can submit his/her proposal to an external granting agency. Then, prior to the intended submission date, all MWU personnel devoting effort to the project must complete and obtain the necessary administrative approvals on Form C (“Conflict of Interest Policy Disclosure Form”).

If a PI is submitting a proposal that includes international travel to be supported by grant funds, approval must be obtained by their college dean and the university president prior to grant submission.

If a PI is submitting a proposal involving a faculty member from another institution, the ORSP staff can assist, but the faculty member is ultimately responsible for obtaining all necessary forms and documents (Budget, Budget Justification, Biographical Sketch, Facilities and Other Resources page, and Letter of Collaboration). The PI must provide ORSP subaward documents including the “Subrecipient Commitment Form” signed by the authorized organization representative of the subawardee institution no fewer than five (5) days prior to grant deadline.

The proposal must include a(n):

- (1) Title
- (2) Abstract
- (3) Research Plan with:
 - a. Specific aims (What do you intend to do?),
 - b. Background and Significance (Why is the work important?),
 - c. Preliminary Studies/Progress Report (What has already been done?),
 - d. Research Design and Methods (How are you going to do the work?), and
- (4) Bibliography

All organized research activities involving animal or human subjects at MWU must be approved by either the IACUC (for non-human subjects research) or the IRB (for human subjects research). Failure to adhere to the MWU research Policy will lead to suspension of the activity until a formal proposal has been approved by appropriate members of the university administration and the required institutional committees.

MWU’s ORSP will require IACUC and/or IRB application or approval at the time of submitting an extramural funding application, only when such a requirement is imposed by the funding agency.

Research involving the use of animals

Investigators planning to use animals in research studies must submit a completed **APPLICATION FOR USE OF ANIMALS - FORM B**, available on the ORSP website, and receive Institutional Animal Care and Use Committee (IACUC) approval prior to initiating any studies with animals. Upon receipt of the application, the proposal will be forwarded to the IACUC for review (for further information on animal research, see Midwestern University policy 6 regarding IACUC policies and procedures). Investigators will be informed of the committee's decision on the application to use animals for biomedical research purposes.

Research involving human subjects

Investigators planning an activity involving human research subjects must submit a completed **APPLICATION FOR INVESTIGATIONS IN HUMAN SUBJECTS -FORM A** (available from the ORSP website), an **Informed Consent** (when required) and receive Institutional Review Board (IRB) approval prior to initiating any studies with human subjects. Upon receipt of the application, the proposal will be forwarded to the IRB for review and action (for further information on human subjects research, see MWU policies 7 and 8 regarding IRB policies and procedures). Investigators will be informed of the committee's decision on the use of human subjects for biomedical or other research purposes.

Research involving biological hazardous materials, recombinant, DNA or radioisotopes

Investigators engaged in research that will involve biologically hazardous materials, recombinant DNA or radioisotopes also must seek appropriate institutional committee approval prior to initiating any research. The ORSP can provide direction in regards to the requirements appropriate for the specific research project.